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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/776,625	01/31/2004	Leone Dall'asta	SAIC 20.931 (100788-00071)	1735
26304	7590	05/30/2006	EXAMINER	
KATTEN MUCHIN ROSENMAN LLP 575 MADISON AVENUE NEW YORK, NY 10022-2585			SOLOLA, TAOFIQ A	
			ART UNIT	PAPER NUMBER
			1626	

DATE MAILED: 05/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/776,625

Applicant(s)

DALL'ASTA ET AL.

Examiner

Taofiq A. Solola

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 27 February 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) 15-23, 26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-14, 24, 25 and 27-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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Claims 1-33 are pending in this application.

Claims 15-23, 26 are drawn to non-elected invention.

Request for Continued Examination

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.117(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/27/06 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-14, 24-25, 27-33 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification lacks adequate support for the claims. The specification fails to provide support that any or all known "optically active acids" are applicable in the instant process. The term R' in claim 1, line 6, is not defined in the specification so as to determine the structures of compounds that are included and/or excluded by the term. The term is defined with the phraseology "such as" on line 15, page 5 of the specification. Therefore, the listed

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compounds are deemed examples only. However, "[e]xemplification is not an explicit definition." The specification must set forth any definition explicitly with reasonable clarity, precision and deliberateness, *Teflex Inc. v. Ficos North Ame. Corp.*, 63 USPQ2d 1374 1381 (Fed Cir, 2001). Applicant must show possession of the invention by describing it with all the claimed limitations. *Lookwood v. American Airlines Inc.* 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed Cir. 1997). By amending the claims to recite the specific optically active acids and compounds represented by R' cited in the specification the rejection would be overcome.

As now amended, claims 1-14, 24-25, 27-33 lack adequate support in the specification. According to the specification, page 3, hydroxylamine is reacted with formula I in step (a) while 4-fluorophenylmagnesium is reacted with formula III in step (b). According to the specification, page 4, step (c) requires reacting 3-(dimethylamino)propyl magnesium halide with formula (IV) in order to obtain formula (V). Step (e) should have been optional because it is not required when R is H, that is, no substitution. These are different from the steps in claim 1.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 1-14, 24-25, 27-33 are rejected under 35 U.S.C. 112, second paragraph, as failing to set forth the subject matter which applicant(s) regard as their invention. Evidence that the claims fail to correspond in the manner with that which applicant(s) regard as the invention is as set forth above under 35 U.S.C. 112, first paragraph.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-14, 24-25, 27-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Guazzi et al., WO 02/48133.

Applicant claims a process of making citalopram from 5-formylphthalide as set forth in steps (a) to (f) in claim 1. In an optional embodiment the H of OH in hydroxylamine (a reagent) can be replaced with any substituent, which is inert under Grignard reaction condition. See the specification at page 5, lines 14-15. Applicant also claims enantiomeric separation of formula V or VI with tartaric acid or camphosulfonic acid.

Determination of the scope and content of the prior art (MPEP §2141.01)

Guazzi et al., teach a similar process of making citalopram (formula I) from 5-formylphthalide (formula VIII). See the reaction scheme at page 4. Guazzi et al., also teach enantiomeric separation of formula V or VI, according to the process of Boegesoe et al., US 4,943,590, (col. 3, step (b)) which is performed with tartaric or camphosulfonic acid. See page 6, lines 17-21.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the instant invention and that of Guazzi et al., is that the first step in applicant's process is the 2nd to the last step in the process of Guazzi et al. Additionally, when there is no substitution at position R', the instant step (a) is the same as Guazzi's step 7; step (b) is step 4; step (c) is step 5; steps d and f are described in step 8 of Guazzi et al. Steps e and e' are optional. The substituents (R') are taught by Guazzi et al., from the last line of page 5 to line 4 of page 6.

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Also, Applicant does not perform the first step of Guazzi et al., i.e. the conversion of 5-formylphthalide to the corresponding acetal (formula VII).

Finding of prima facie obviousness--rational and motivation (MPEP §2142.2413)

All the reagents in the instant steps are the same as that of Guazzi et al. Therefore, the instant process is no more than a selective combination of the process of Guazzi et al., done in a manner obvious to one of ordinary skill in the art. Selective combination of prior art(s) teaching is prima facie obvious. There is no indication of an interaction between the steps such that one of ordinary skill in the art would have any doubts that the selective combinations could not be made. *In re Mostovich*, 144 USPQ 38 (CCPA, 1964).

Priority Document

Applicant claims priority to a PCT and a foreign document. However, the English Language translations of the documents are not yet received.

This is an RCE of an earlier Application. All claims are drawn to the same invention claimed in the earlier application and were finally rejected on the grounds and art of record in this Office action. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taofiq A. Solola, PhD. JD., whose telephone number is (571) 272-0709.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph McKane, can be reached on (571) 272-0699. The fax phone number for this Group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.



**TAOFIQ SOLOLA
PRIMARY EXAMINER**

Group 1626

May 16, 2006